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<b>TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371</b>		<b>ATTORNEY'S DOCKET NUMBER</b> 06439/HG
<b>INTERNATIONAL APPLICATION NO.</b> PCT/JP2005/002884	<b>INTERNATIONAL FILING DATE</b> 23 FEBRUARY 2005	<b>U.S. APPLICATION NO. (If known, see 37 CFR 1.5)</b> 10/588,818
<b>TITLE OF INVENTION</b> AMINO ALCOHOL COMPOUND		<b>PRIORITY DATE CLAIMED</b> 24 FEBRUARY 2004
<b>APPLICANT(S) FOR DO/EO/US</b> Takahide NISHI; Toshiyasu TAKEMOTO; Shojiro MIYAZAKI; Takaichi SHIMOZATO; Futoshi NARA; Takashi IZUMI		
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:		
<p>1. <input type="checkbox"/> This is a <b>FIRST</b> submission of items concerning a submission under 35 U.S.C. 371.</p> <p>2. <input checked="" type="checkbox"/> This is a <b>SECOND</b> or <b>SUBSEQUENT</b> submission of items concerning a submission under 35 U.S.C. 371.</p> <p>3. <input type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.</p> <p>4. <input type="checkbox"/> The US has been elected (Article 31).</p> <p>5. <input type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2)).</p> <p>a. <input type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau).</p> <p>b. <input type="checkbox"/> has been communicated by the International Bureau.</p> <p>c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US).</p> <p>6. <input type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).</p> <p>a. <input type="checkbox"/> is attached hereto.</p> <p>b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4).</p> <p>7. <input type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)).</p> <p>a. <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau).</p> <p>b. <input type="checkbox"/> have been communicated by the International Bureau.</p> <p>c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired.</p> <p>d. <input type="checkbox"/> have not been made and will not be made.</p> <p>8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).</p> <p>9. <input type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).</p> <p>10. <input type="checkbox"/> An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).</p> <p><b>Items 11 to 20 below concern document(s) or information included:</b></p> <p>11. <input checked="" type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98.</p> <p>12. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.</p> <p>13. <input type="checkbox"/> A preliminary amendment.</p> <p>14. <input type="checkbox"/> An Application Data Sheet under 37 CFR 1.76.</p> <p>15. <input type="checkbox"/> A substitute specification.</p> <p>16. <input type="checkbox"/> A power of attorney and/or change of address letter.</p> <p>17. <input type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821- 1.825.</p> <p>18. <input type="checkbox"/> A second copy of the published International Application under 35 U.S.C. 154(d)(4).</p> <p>19. <input type="checkbox"/> A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).</p> <p>20. <input type="checkbox"/> Other items or information:</p>		

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DATE OF DEPOSIT: SEPTEMBER 25, 2006

I hereby certify that this paper is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above with sufficient postage, and is addressed to the Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

*Dorothy DeFrancesco*  
Dorothy DeFrancesco

U.S. APPLICATION NO. (if known, see 37 CFR 1.5) <b>10/588,818</b>		INTERNATIONAL APPLICATION NO. <b>PCT/JP2005/002884</b>		ATTORNEY'S DOCKET NUMBER <b>06439/HG</b>	
The following fees have been submitted				CALCULATIONS PTO USE ONLY	
21. <input type="checkbox"/> Basic national fee..... \$300				\$	
22. <input type="checkbox"/> Examination fee If international preliminary examination report prepared by USPTO and all claims satisfy provisions of PCT Article 33(1)-(4)..... \$0 All other situations..... \$200				\$	
23. <input type="checkbox"/> Search fee Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority..... \$100 International Search Report prepared and provided to the Office..... \$400 All other situations..... \$500				\$	
<b>TOTAL OF 21, 22 and 23 =</b>				\$	
<input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.					
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CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	\$	
Total claims	- 20 =		x \$ 50	\$	
Independent claims	- 3 =		x \$200	\$	
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ \$360	\$	
<b>TOTAL OF ABOVE CALCULATIONS =</b>				\$	
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2.					
<b>SUBTOTAL =</b>				\$	
Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(l)).				\$	.00
<b>TOTAL NATIONAL FEE =</b>				\$	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property				\$	
<b>TOTAL FEES ENCLOSED =</b>				\$	1790.00
				Amount to be refunded:	\$ .00
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<p>a. <input type="checkbox"/> A check in the amount of \$ _____ to cover the above fees is enclosed.</p> <p>b. <input type="checkbox"/> Please charge my Deposit Account No. _____ in the amount of \$ _____ to cover the above fees.</p> <p>c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. <u>06-1378</u>.</p> <p>d. <input type="checkbox"/> Fees are to be charged to a credit card. <b>WARNING:</b> Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.</p>					
<p><b>NOTE:</b> Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the international application to pending status.</p>					
<p>SEND ALL CORRESPONDENCE TO:</p> <p><b>CUSTOMER NO. 01933</b></p> <p>Richard S. Barth Frishauf, Holtz, Goodman &amp; Chick P.C. 220 5TH AVE FL 16 NEW YORK NY 10001-7708 SEPTEMBER 25, 2006</p>					
				<p><i>Richard Barth</i></p> <p>SIGNATURE</p> <p><b>Richard Barth</b></p> <p>NAME</p> <p><b>28,180</b></p> <p>REGISTRATION NUMBER</p>	

**IN THE UNITED STATES PATENT  
AND TRADEMARK OFFICE**

Serial No. : 10/588,818  
Filed : August 9, 2006  
Applicants : Takahide NISHI et al.  
For : AMINO ALCOHOL COMPOUND  
Docket No. : 06439/HG  
Customer No.: 01933  
Confirm. No.: 2782

**INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**MAIL STOP PCT**

S I R :

This application is the United States national phase application of International application PCT/JP2005/002884.

A copy of the International Search Report (in English) for International application PCT/JP2005/002884 was submitted in the above-identified application with the INFORMATION DISCLOSURE STATEMENT filed on August 9, 2006.

Submitted concomitantly herewith are the following:

(1) a copy of a publication (JP 2005-041867) cited in the aforesaid International Search Report;

(2) copies of publications which are related family members of publications disclosed on pages 2 to 6 of the present specification; and

Express Mail Mailing Label  
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P.O. Box 1450  
Alexandria, VA 22313-1450

  
Dorothy DeFrancesco

In the event that this Paper is late filed, and the necessary petition for extension of time is not filed concurrently herewith, please consider this as a Petition for the requisite extension of time, and to the extent not tendered by Form PTO-2038 attached hereto, authorization to charge the extension fee, or any other fee required in connection with this Paper to Account No. 06-1378.

(3) Forms PTO/SB/08A and PTO/SB/08B.

Each of the publications cited in said International Search Report is considered relevant or material to the patentability of the present invention, in view of the citation thereof in said International Search Report.

Said International Search Report is in English, thereby satisfying the requirements for a concise explanation of relevance.

In the INFORMATION DISCLOSURE STATEMENT filed on August 9, 2006, US 2005/0043386 was cited. US 2005/0043386 is a related family member of JP 2003-267950, which was cited in said International Search Report and is disclosed in the present specification.

The enclosed EP 0 627 406 is a related family member of WO 94/08943.

The enclosed EP 0 778 263 is a related family member of WO 96/06068.

The enclosed EP 1 002 792 is a related family member of WO 98/45249.

US 2004/0242654 is a related family member of WO 03/029184.

US 2004/025222 is a related family member of WO 029205.

US 2003/0236297 is a related family member of JP 2002-167382A.

It is respectfully requested that initialed copies of the enclosed Forms PTO/SB/08A and PTO/SB/08B be returned to the undersigned to indicate that the publications listed therein have been considered and made of record.

Respectfully submitted,

A handwritten signature in dark ink, appearing to read "Richard Barth", written over a horizontal line.

RICHARD S. BARTH  
REG. NO. 28,180

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RSB/ddf

Encs.: Forms PTO/SB/08A and PTO/SB/08B and  
copies of the non-US patent documents  
cited therein

Please type a plus sign (+) inside this box →

+

PTO/SB/08A (08-00)

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Substitute for Form 1449A/PTO  INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	10/588,818
				Filing Date	August 9, 2006
				First Named Inventor	Takahide NISHI
				Group Art Unit	
				Examiner Name	
Sheet	1	of	2	Attorney Docket Number	06439/HG

## U.S. PATENT DOCUMENTS

Exam. Inits <sup>*</sup>	Cite No <sup>1</sup>	Document Number	Kind Code <sup>2</sup>	Name of Patentee or Applicant	Publication Date MM-DD-YYYY	Relevant Portion
		2004/0242654	A1	KOHNO et al.	12-2-2004	
		2004/0254222	A1	KOHNO et al.	12-16-2004	
		2003/0236297	A1	NISHI et al.	12-25-2003	

## FOREIGN PATENT DOCUMENTS

Exam. Inits <sup>*</sup>	Cite No <sup>1</sup>	Offc <sup>3</sup>	Document Number <sup>4</sup>	Kind Code <sup>5</sup>	Name of Patentee or Applicant	Publication Date MM-DD-YYYY	Relevant Portion	T <sup>6</sup>
		JP	2005-41867	A	SANKYO CO., LTD.	2-17-2005		*
		EP	0 627 406	A1	YOSHITOMI PHARMACETICAL INDUSTRIES, LTD.	12-7-1994		
		EP	0 778 263	A1	YOSHITOMI PHARMACEUTICAL INDUSTRIES, LTD.	6-11-1997		
		EP	1 002 792	A1	YOSHITOMI PHARMACEUTICAL INDUSTRIES, LTD.	5-24-2000		

Examiner Signature		Date Considered	
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\* EXAMINER: Initial if document considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Place a check here if English translation is attached.

DATE: September 25, 2006 \*ENGLISH-LANGUAGE ABSTRACT ENCLOSED.

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PTO/SB/08B (08-00)

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Substitute for Form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>				Application Number		10/588,818	
				Filing Date		August 9, 2006	
				First Named Inventor		Takahide NISHI	
				Group Art Unit			
				Examiner Name			
Sheet	2	of	2	Attorney Docket Number		06439/HG	
<b>OTHER DOCUMENTS - NON-PATENT LITERATURE DOCUMENTS</b>							
Examiner Initials <sup>1</sup>	Cite No. <sup>1</sup>	Include name of author (in CAPITAL LETTERS), title of article, title of item, date, page(s), volume-issue number(s), publisher, city and/or country where published					T <sup>2</sup>
		Xiao-Ru Huang et al., "Th1 responsiveness to nephritogenic antigens determines susceptibility to crescentic glomerulonephritis in mice," <u>Kidney International</u> , Vol. 51, (1997), pp. 94-103.  Monique A. BERMAN et al., "Decreased IL-4 Production in new Onset Type 1 Insulin-Dependent Diabetes Mellitus," <u>The Journal of Immunology</u> , Vol. 157, 4691 (1996).					
Examiner Signature					Date Considered		

\* EXAMINER: Initial if document considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> Place a check here if English translation is attached.

DATE: September 25, 2006